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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,470	11/20/2003	Yoshiya Gunji	US-103	5760
38108 7590 06/01/2007 CERMAK & KENEALY LLP ACS LLC 515 EAST BRADDOCK ROAD SUITE B ALEXANDRIA, VA 22314			EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/716,470

**Applicant(s)**

GUNJI ET AL.

**Examiner**

Delia M. Ramirez

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

Claims 1, 8-12 are pending.

Applicant's amendment of claims 1, 9, cancellation of claims 2-7, addition of claims 10-12, and amendments to the specification as submitted in a communication filed on 3/22/2007 are acknowledged.

Claim 10 is deemed directed to the elected subject matter. Claims 1 and 10 are at issue and are being examined herein. Since claims 1 and 10 are not allowable at this time, the restriction requirement between product and process claims can be properly maintained. Claims 8-9, 11-12 are directed to non-elected subject matter and are being withdrawn from consideration.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 7, 9, 11 of copending Application No. 11/563289.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

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Claims 1 and 10 of the instant application are directed to a *Methylobacillus* cell which comprises a DNA (1) encoding the polypeptide of SEQ ID NO: 10, or (2) comprising SEQ ID NO: 9. The specification of the instant application discloses that (1) the polynucleotide of SEQ ID NO: 9 is designated as the lysE24 gene and encodes the polypeptide of SEQ ID NO: 10 (paragraph [92]), and (2) the lysE24 gene is a mutant of the *Brevibacterium lactofermentum* 2256 strain lysE gene which comprises a nonsense mutation which introduces a stop codon around the center of the translation region of lysE (paragraph [91]). Claims 5, 7, 9, 11 of copending Application No. 11/563289 are directed to a *Methylobacillus* cell which comprises (1) the lysE24 gene integrated into the chromosome, or (2) the lysE24 gene in a plasmid. The specification of copending application No. 11/563289 discloses that lysE24 is a mutant of the *Brevibacterium lactofermentum* 2256 strain lysE gene which comprises a nonsense mutation that introduces a stop codon in the middle of the translation region of lysE (paragraph [82], [88], [100]). The sequence listing of copending application No. 11/563289 discloses SEQ ID NO: 9 and 10 as having the same number of nucleotides and amino acids as SEQ ID NO: 9 and 10 of the instant application. Therefore, the cell of claims 5, 7, 9, 11 of copending Application No. 11/563289 anticipates the cell of claims 1 and 10 of the instant application as written.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of U.S. Patent No. 7169587. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

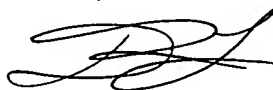
Claims 1 and 10 of the instant application are directed to a *Methylobacillus* cell which comprises a DNA (1) encoding the polypeptide of SEQ ID NO: 10, or (2) comprising SEQ ID NO: 9. Claims 8-11 of U.S. Patent No. 7169587 are directed to a *Methylobacillus* cell which comprises (1) a plasmid

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containing a DNA comprising SEQ ID NO: 9, (2) a plasmid containing a DNA encoding the polypeptide of SEQ ID NO: 10, and (3) a DNA encoding the polypeptide of SEQ ID NO: 10 wherein the DNA is integrated into the chromosome of the cell. Upon conducting a sequence search, it was found that SEQ ID NO: 9 and 10 in the instant application and U.S. Patent No. 7169587 are identical. Therefore, the cell of claims 8- 11 of U.S. Patent No. 7169587 anticipates the cell of claims 1 and 10 of the instant application as written.

***Conclusion***

4. No claim is in condition for allowance.
5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.  
Primary Patent Examiner  
Art Unit 1652

DR  
May 25, 2007